Hoechst Marion Roussel, Inc.

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July 20, 1998

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., Rm. 1-23
Rockville, MD 20857

Subject: Docket No. 98N-0222

Dear Sirs:

Hoechst Marion Roussel has the following comments regarding the proposed rule on dissemination of information on unapproved/new uses for marketed drugs, biologics, and devices, which was published in the June 8 Federal Register.

Definition of "new use"

"New use", as defined by proposed Sec. 99.3(g), is a "use that is not included in the approved labeling of an approved drug or device . . .". However, as described in the preamble to the proposed rule, this includes, among other things, "comparative claims to other agents for treatment of the same condition." This interpretation conflicts with current FDA regulations.

Under the proposed definition in the preamble, a reprint of a comparative study could only be disseminated if the requirements of this rule regarding supplemental applications or exemptions, submissions of information to be disseminated, record keeping, reporting, etc. are followed.

However, current advertising regulations permit comparative claims as long as they concern an approved indication, are not false or misleading, and the comparisons are supported by substantial evidence or substantial clinical experience. (For example, see 21 CFR 202.1(e)(6)(ii), which says that advertisements are misleading if they contain a comparison that suggests that a drug is more effective than another drug when it has not been demonstrated by substantial evidence or substantial clinical experience. See also April 1994 FDA/DDMAC Guidance Letter to Industry.) Current regulations (21 CFR 202.1(l)(2)) also define promotional labeling to include reprints. Thus, dissemination of comparative reprints is allowed by current promotional regulations. There is no requirement that the comparative study be described in the approved labeling.

We believe that the definition of "new use" is too broad, that it should focus on information that *differs from* the current labeling, and that it should *not* include

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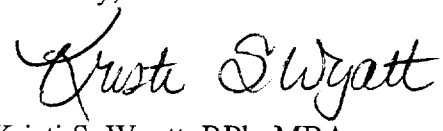
information that is *consistent with, but more detailed than* what is described in the approved labeling.

Reference publications

The preamble to the proposed rule discusses the requirement for the disseminated information to be about a clinical investigation, concludes that the majority of reference texts would not meet that requirement, and states that FDA, therefore, plans to develop a draft guidance on reference publications that do not fall within the scope of part 99. We request that FDA clarify the status of the textbook guidance that was published in October 1996 (61 FR 52800), Guidance for Industry Funded Dissemination of Reference Texts. Manufacturers should be able to continue to distribute textbooks under that guideline once Section 401 of FDAMA becomes effective.

Sincerely,



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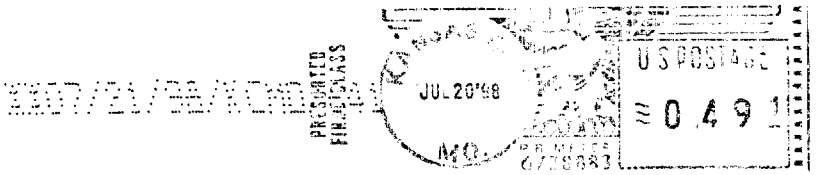

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